

Exhibit 1

STATE OF MINNESOTA

DISTRICT COURT

COUNTY OF HENNEPIN

FOURTH JUDICIAL DISTRICT
Case Type: Civil Other

Amanda Seutter and Brittany Yelle,
individually and on behalf of a class of
similarly situated individuals,

Plaintiffs,

v.

MEAD JOHNSON NUTRITION
COMPANY and MEAD JOHNSON &
COMPANY, LLC,

Defendants.

Court File No. _____

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

1. Plaintiffs Amanda Seutter and Brittany Yelle (“Plaintiffs”), individually and on behalf of all others similarly situated, by and through their undersigned attorneys, bring this Class Action Complaint against Defendant Mead Johnson Nutrition Company and Defendant Mead Johnson & Company, LLC (collectively, “Defendant” or “Mead Johnson”), for its knowing, reckless, and/or intentional practice of failing to disclose the presence or material risk of Heavy Metals in its Enfamil® infant formulas (“Products” or “Infant Formulas”).¹ The Infant Formulas are sold in Minnesota and throughout the United States and do not conform to their packaging.

¹ As used herein, “Heavy Metals” includes arsenic, cadmium, and lead. “Products” or “Infant Formula(s)” as to the Heavy Metals allegations refer to the following Mead Johnson powdered infant formula products: Enfamil A.R., Enfamil Gentlelease, Enfamil Enspire Gentlelease, Enfamil NeuroPro, Enfamil NeuroPro Sensitive, Enfamil Nutramigen, and Enfamil ProSobee. Discovery may reveal additional products that contain Heavy Metals and/or the presence of additional heavy metals. Plaintiffs reserve their right to amend and include any such additional products or heavy metals in this action.

Plaintiffs seek both injunctive and monetary relief on behalf of the proposed Class (as defined herein), including requiring full disclosure of the risk or presence of Heavy Metals on the Products' packaging, and restoring monies to the members of the proposed Class. Plaintiffs allege the following based upon personal knowledge as well as investigation by their counsel as to themselves, and as to all other matters, upon information and belief. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

2. Mead Johnson is one of the primary manufacturers of infant formula in the United States and previously held 39.6% of the market share for powdered infant formula.² As a trusted manufacturer and vendor of products consumed exclusively by babies and young children, it carries a duty of the highest importance to implement and maintain quality control when manufacturing its products. When a company selling vital products, such as Defendant who sells infant formula, it must not knowingly fail to ensure the safety of its products and must not allow dangerous toxins or contaminants, such as Heavy Metals, to be consumed by its unsuspecting consumers. Rather, these companies have a duty to disclose material risks of contamination—allowing consumers to make informed decisions about the risks they are willing to take (especially with the health of their infants) and assess the true value of the product they are considering for purchase. Defendant failed to do so in this case.

3. Defendant's Products contain dangerous toxins: Heavy Metals. As detailed below, individuals, especially infants, who consume Heavy Metals risk developing serious adverse health

² *Market Share of the Leading Vendors of Baby Formula (Powder) in the United States in 2016, Based on Dollar Sales*, available at <https://www.statista.com/statistics/443975/market-share-of-the-leading-us-baby-formula-powder-companies/> (last accessed April 29, 2024).

effects – a risk which most consumers strongly prefer to avoid in food they feed children (who are more vulnerable to those risks than others). Yet, Defendant chose to sell itself to new parents as a trusted company, without disclosing that its formula contained or had a material risk of containing Heavy Metals (collectively, the “Omissions”), which would be material to any parent purchasing formula for their infant.

4. Infants rely on breastmilk and/or infant formula for their nutrition and growth. The U.S. Dietary Guidelines for Americans and the American Academy of Pediatrics recommends breastfeeding babies exclusively for about six months from birth and continuing afterwards along with introduction of solid foods until they are 12 months old and beyond.³ However, according to the Centers for Disease Control and Prevention (“CDC”), only 46.3% of babies under three months old are exclusively breastfed, and the percentage of babies exclusively breastfed through six months drops to 25.8%.⁴ For babies younger than six months, the CDC recommends that breast milk or infant formula are the only things they eat for their nutrition, and while supplementing with some solid food, breastmilk or infant formula is recommended up to when they are 24 months old.⁵ Therefore, a significant number of babies rely on infant formulas for their growth and nutrition in the first year of their lives and beyond.

5. Reasonable parents, like Plaintiffs, trust and depend on manufacturers, like Defendant, to sell infant formula that is healthy, nutritious, and free from the presence or material

³ CDC, *Infant and Toddler Nutrition: Recommendation and Benefits*, available at <https://www.cdc.gov/nutrition/infantandtoddlernutrition/breastfeeding/recommendations-benefits.html> (last accessed January 21, 2024).

⁴ CDC, *Facts: Key Breastfeeding Indicators*, available at <https://www.cdc.gov/breastfeeding/data/facts.html> (last accessed March 18, 2024).

⁵ CDC, *When, What, and How to Introduce Solid Foods*, available at <https://www.cdc.gov/nutrition/InfantandToddlerNutrition/foods-and-drinks/when-to-introduce-solid-foods.html> (last accessed March 18, 2024).

risk of harmful toxins, contaminants, and chemicals. They certainly expect the formula they feed their infants to be free of the risk or presence of Heavy Metals, substances known to have significant and unsafe developmental and health consequences as detailed herein.

6. Consumers lack the knowledge and opportunity to determine whether Defendant's Products do in fact contain (or have a material risk of containing) Heavy Metals or to ascertain the true nature of the ingredients and quality of the Products. Reasonable consumers therefore must and do rely on Defendant to properly and fully disclose what its Products contain. This is especially true for the risk or presence of Heavy Metals that are being fed to hours-, days- or months-old babies. Such information would be material to any reasonable parent's purchasing decisions.

7. Defendant's packaging is designed to induce reasonable consumers to believe in the high quality and safety of its infant formula while omitting any information about the inclusion (or material risk of inclusion) of Heavy Metals.

8. For example, the packaging emphasizes that the Infant Formulas are healthy and made with nutritious ingredients that help support proper development and growth:⁶



⁶ <https://www.enfamil.com/products/enfamil-neuropro-infant-formula/powder-tub-20-7-oz-tub/> (last accessed March 18, 2024).

9. The packaging on the Infant Formulas also stresses that there are no detrimental, harmful, and genetically engineered ingredients:⁷



10. On these packages and others, Defendant states the Infant Formulas contain nutritious ingredients such as Docosahexaenoic Acid ("DHA"), prebiotics such as human milk oligosaccharides ("HMO"), probiotics, and desirable (naturally occurring) minerals such as selenium.



⁷ <https://www.enfamil.com/products/enfamil-neuropro-gentlease-formula/powder-tub-19-5-oz-tub/> (last accessed March 18, 2024).

11. Based on the messaging and impression communicated by the packaging and the material nondisclosures, no reasonable consumer could expect or understand that the Infant Formulas contained or risked containing Heavy Metals. This is especially true as the development and physical risks created by ingestion of Heavy Metals by infants are well-recognized.

12. Likewise, this same packaging promising healthy, high quality and safe products would not lead reasonable consumers to expect or understand that the Infant Formulas were manufactured by a company that allowed improper quality control procedures.

13. Defendant's website provides further context to demonstrate that the Products' packaging is deceptive by promising a healthy product that poses no risks to any infants. Specifically, Defendant promises on its website that: (1) Defendant “[s]upport[s] the brain in everything” it does with products that “are excellent for routine, everyday feeding;”⁸ (2) “[t]he health and safety of infants and children is [Defendant’s] top priority,” and it is “committed to providing a high quality and safe products [sic] for [its] littlest consumers;”⁹ (3) Defendant’s “products undergo extensive quality and safety checks throughout the manufacturing process—from raw materials to finished product” and that “samples from every batch [it] produce[s] are tested to ensure the product meets [its] stringent quality standards;”¹⁰ and (4) “[p]arents can be assured that our infant formulas are safe and nutritious feeding options for their infants.”¹¹ These representations are each in direct contradiction to the Omissions.

⁸ <https://www.enfamil.com/why-enfamil/enfamil-formula-family/> (last accessed March 18, 2024).

⁹ <https://www.enfamil.com/why-enfamil/quality-assurance/> (last accessed March 18, 2024).

¹⁰ *Id.*

¹¹ *Id.*

14. On information and belief, Defendant was knowingly, recklessly, and/or intentionally selling Infant Formulas that contained or risked containing detectable levels of arsenic, cadmium, and/or lead.

15. Independent testing also confirmed the presence of Heavy Metals in two of Defendant's Infant Formulas:¹²

Infant Formula	Arsenic (ppb)	Cadmium (ppb)	Lead (ppb)
Enfamil ProSobee Soy Infant Formula	6.2*	6.9	7.8
Enfamil Infant – Infant Formula Milk-Based with Iron, 0-12 months	< 2.2	0.7*	2.0

16. Arsenic, cadmium, and lead are all known to pose health risks to humans, and particularly to infants.¹³

17. Exposure to Heavy Metals has significant and dangerous health consequences. A 2021 report by the U.S. House of Representatives' Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform highlighted the material risk of including Heavy Metals in baby food, spurred by the knowledge that “[e]ven low levels of exposure can cause serious and often irreversible damage to brain development.”¹⁴

¹² Healthy Babies Bright Futures' Report: *What's in My Baby's Food?*, at 20, available at https://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2020-04/BabyFoodReport_ENGLISH_R6.pdf (last accessed March 18, 2024) (“HBBF Report”)..

¹³ See generally, *id.*

¹⁴ U.S. House of Representatives, Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, Staff Report, “Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury,” February 4, 2021, available at <https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf> (last accessed March 18, 2024)

18. Despite the known health risks, Defendant knowingly chose to not disclose to consumers that the Infant Formulas contain (or have a material risk of containing) Heavy Metals. Nowhere on the Infant Formulas' packaging is it disclosed that they contain (or have a material risk of containing) Heavy Metals.

19. The Infant Formulas' packaging does not include any type of disclaimer or disclosure regarding the presence of Heavy Metals that would inform consumers of their presence or risk. Likewise, nothing on the packaging states that ingestion of Heavy Metals can be unsafe or accumulate over time resulting in developmental issues, poisoning, injury, and/or disease.

20. Instead, to induce reasonable consumers to believe in the quality and safety of its Products and to justify a price that reflects a premium, Defendant chose to focus on promoting its Infant Formulas on its packaging as high quality and made with nutritious ingredients.

21. Defendant's marketing strategy reflects the concerns raised by the World Health Organization ("WHO") and UNICEF in their report acknowledging the troubling marketing efforts by infant formula milk manufacturers.¹⁵ This report raises deep concerns over the lasting and pervasive negative effects from the false and misleading information received by parents such as

(“Congressional Committee Report”); *see also* U.S. House of Representatives, Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, Staff Report, “New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby Foods,” September 29, 2021, available at <https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/ECP%20Second%20Baby%20Food%20Report%209.29.21%20FINAL.pdf> (last accessed March 18, 2024) (“Second Congressional Committee Report”).

¹⁵ WHO, *How the Marketing of Formula Milk Influences our Decisions on Infant Feeding*, February 22, 2022, available at <https://www.who.int/teams/maternal-newborn-child-adolescent-health-and-ageing/formula-milk-industry> (last accessed March 18, 2024).

Plaintiffs and the Class members through such aggressive marketing efforts by infant formula manufacturers such as Defendant.¹⁶

22. Based on Defendant's packaging and related omissions, no reasonable consumer had any reason to know or expect that the Infant Formulas contained Heavy Metals. Furthermore, reasonable parents, like Plaintiffs and the Class members, who were feeding the Infant Formulas to their babies (multiple times a day) would consider the mere presence (or risk) of Heavy Metals a material fact when considering whether to purchase the Infant Formulas.

23. Defendant knows its customers trust the quality of its Products that are manufactured for the most vulnerable population – infants – and expect the Infant Formulas to be properly and safely manufactured and free from the risk and actual presence of Heavy Metals. Defendant also knows its consumers seek out and wish to purchase infant formulas that possess nutritious ingredients free of toxins, contaminants, or chemicals, and that these consumers will pay for infant formulas they believe possess these qualities. Defendant also knows no reasonable consumer would knowingly provide his or her children with infant formula that contained Heavy Metals.

24. Defendant knew that parents would find the Omissions material when deciding whether to purchase the Infant Formulas and that it was in a special position of public trust to those consumers.

¹⁶ National Public Radio, *Infant Formula Promoted in 'Aggressive' and 'Misleading' Ways, Says New Global Report*, March 1, 2022, available at <https://www.npr.org/sections/goatsandsoda/2022/03/01/1082775961/infant-formula-promoted-in-aggressive-and-misleading-ways-says-new-global-report> (last accessed March 18, 2024).

25. The material Omissions are deceptive, misleading, unfair, and/or false because the Infant Formulas were manufactured in a such a way that they contained (or risked containing) undisclosed Heavy Metals.

26. The Omissions allowed Defendant to capitalize on, and reap enormous profits from, reasonable consumers who paid a premium price for Infant Formulas that did not disclose material information as to the Products' true quality and value. Defendant continues to wrongfully induce consumers to purchase its Infant Formulas without full disclosure of the Omissions.

27. Plaintiffs bring this proposed consumer class action individually and on behalf of all other members of the Class (as defined herein), who, from the applicable limitations period up to and including the present, purchased for household use and not resale any of Defendant's Infant Formulas.

JURISDICTION AND VENUE

28. This Court has subject matter jurisdiction over this action as it is based on Minnesota Statute sections 8.31, 336.2-314, 325D.09 to 325D.16, 325D.43 to 325D.48, 325F.67, 325F.68 to 325F.70, and Minnesota common law.

29. This Court has personal jurisdiction over Defendant as it conducts a substantial part of its operations with regular and continuous business activity in Minnesota, on information and belief, through its marketing and retail of the Products. This Court has personal jurisdiction over the Plaintiffs as they both were, and still are, residents of Minnesota during the occurrence of the acts and transactions giving rise to this action and they purchased the Infant Formulas in this State.

30. Venue is proper in Hennepin County because Plaintiff Yelle suffered injury as a result of Defendant's acts in this County, and many of the acts and transactions giving rise to this action occurred in this County.

PARTIES

31. Plaintiff Amanda Seutter (“Plaintiff Seutter”) is, and at times relevant hereto was, a resident of Elk River, Minnesota and currently resides in Hennepin County in the State of Minnesota. She purchased the Infant Formula, including Enfamil® Gentlelease, for household use.

32. Plaintiff Seutter purchased the Infant Formula for her child from Target in Otsego, Minnesota and Amazon.com, from approximately October 2022 until January 2024.

33. Plaintiff Seutter believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Seutter saw and relied upon the packaging of the Infant Formula. During the time she purchased and fed her child the Infant Formula, and due to the Omissions by Defendant, she was unaware the Infant Formulas contained (or had a material risk of containing) Heavy Metals and would not have purchased the Infant Formulas if that information had been fully disclosed. Plaintiff Seutter would be willing to purchase Enfamil® products in the future if she could be certain that they do not contain (or have a material risk of containing) Heavy Metals.

34. As a result of Defendant’s intentionally, recklessly, and/or knowingly deceptive conduct as alleged herein, Plaintiff Seutter was injured when she paid the purchase price or a price premium for the Infant Formula that did not deliver what was promised by Defendant. Plaintiff Seutter paid the purchase price on the reasonable assumptions that the packaging was accurate, the Infant Formulas were free of Heavy Metals, and posed no potential harm to the physical and mental growth of her infant – long term or short term. Plaintiff Seutter would not have paid this money had she known the truth about the Omissions. Further, should Plaintiff Seutter encounter the Infant Formulas in the future, she could not rely on the truthfulness of the packaging, absent corrective

changes to the packaging and advertising of the Infant Formulas. Damages can be calculated through expert testimony at trial.

35. Plaintiff Brittany Yelle (“Plaintiff Yelle”) is, and at times relevant hereto was, a resident of Plymouth, Minnesota and currently resides in Hennepin County in the State of Minnesota. She purchased the Infant Formula, including Enfamil® Neuropro and Enfamil® Gentlease for household use.

36. Plaintiff Yelle purchased the Infant Formula for her child from Target locations in Medina and Minnetonka, Minnesota, from approximately December 2023 through April 2024.

37. Plaintiff Yelle believed she was feeding her child healthy and nutritious Infant Formula. Prior to purchasing the Infant Formula, Plaintiff Yelle saw and relied upon the packaging of the Infant Formula. During the time she purchased and fed her child the Infant Formula, and due to the Omissions by Defendant, she was unaware the Infant Formulas were manufactured without proper quality control procedures and contained (or had a material risk of containing) Heavy Metals and would not have purchased the Infant Formulas if that information had been fully disclosed. Plaintiff Yelle would be willing to purchase Defendant’s Products in the future if she could be certain that they were safely manufactured and do not contain (or have a material risk of containing) Heavy Metals.

38. As a result of Defendant’s intentionally, recklessly, and/or knowingly deceptive conduct as alleged herein, Plaintiff Yelle was injured when she paid the purchase price or a price premium for the Infant Formula that did not deliver what was promised by Defendant. Plaintiff Yelle paid the purchase price on the reasonable assumptions that the packaging was accurate, the Infant Formulas were manufactured with proper quality control procedures, were free of Heavy Metals, and posed no potential harm to the physical and mental growth of her infant – long term

or short term. Plaintiff Yelle would not have paid this money had she known the truth about the Omissions. Further, should Plaintiff Yelle encounter the Infant Formulas in the future, she could not rely on the truthfulness of the packaging, absent corrective changes to the packaging and advertising of the Infant Formulas. Damages can be calculated through expert testimony at trial.

39. Defendant Mead Johnson Nutrition Company is a Delaware corporation with its principal place of business located at 2400 West Lloyd Expressway, Evansville, Indiana. In June 2017, Mead Johnson Nutrition Company was acquired by Reckitt Benckiser Group PLC, whose U.S. headquarters is located at 399 Interpace Parkway, Parsippany, New Jersey. Mead Johnson & Company, LLC, is a Delaware corporation with its headquarters at 2400 West Lloyd Expressway in Evansville, Indiana.

40. Defendant, one of the largest producers of infant formula products in the world, has formulated, developed, manufactured, packaged, labeled, distributed, marketed, advertised, and sold the Infant Formulas under the Enfamil® name throughout the United States, including in this State. Defendant has done so continuously from May 1, 2018, to the present (the “Relevant Period”).

41. Defendant knowingly created, allowed, oversaw, and/or authorized the unlawful, fraudulent, unfair, misleading, and/or deceptive packaging and related marketing for the Infant Formulas that did not disclose the presence (or risk) of Heavy Metals in the Infant Formulas. Defendant is also responsible for sourcing ingredients, manufacturing the Products, and conducting all relevant quality assurance protocols, including testing of both the Products and their ingredients.

42. Plaintiffs relied upon the Infant Formulas’ packaging and the material Omissions, which was disseminated by Defendant and its agents in this State through the material Omissions

from the packaging. The Omissions were nondisclosed material content that a reasonable consumer would consider important in purchasing the Infant Formulas.

43. The Infant Formulas, at a minimum, include:

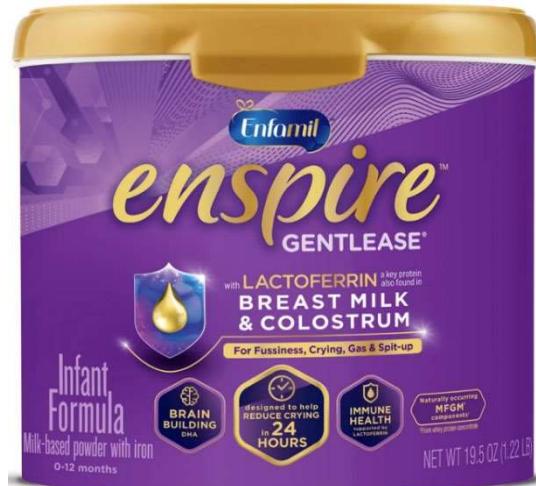
(a) Enfamil® A.R.;



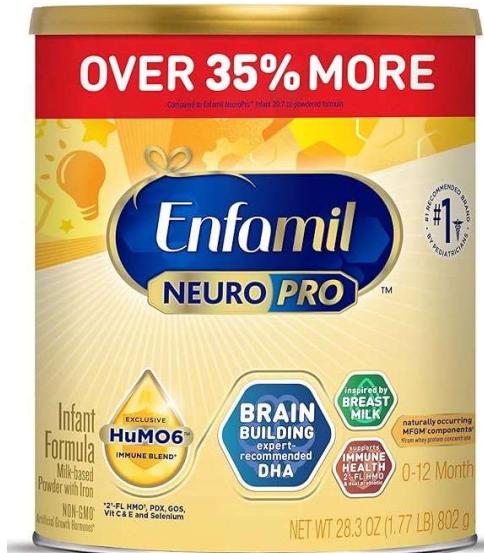
(b) Enfamil® Gentlease;



(c) Enfamil® Enspire Gentlelease;



(d) Enfamil® NeuroPro;



(e) Enfamil® NeuroPro Sensitive;



(f) Enfamil® Nutramigen; and



(g) Enfamil® ProSobee.



FACTUAL ALLEGATIONS

I. DEFENDANT KNEW OR SHOULD HAVE KNOWN OF THE HEALTH RISKS PRESENTED TO INFANTS AND BABIES FROM HEAVY METALS AND THE LIKELIHOOD THEY WERE PRESENT IN ITS PRODUCTS

44. While there are no U.S. federal regulations regarding Heavy Metals in infant formulas, it is not due to a lack of risk. According to Linda McCauley, Dean of the Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental health effects, “No level of exposure to these [heavy] metals has been shown to be safe in vulnerable infants.”¹⁷

45. Arsenic, cadmium, and lead—the Heavy Metals found in the Infant Formulas—are neurotoxins, or poisons, which affect the nervous system. Exposure to these Heavy Metals

¹⁷ New York Times, *Some Baby Food May Contain Toxic Metals, U.S. Reports*, available at <https://www.nytimes.com/2021/02/04/health/baby-food-metals-arsenic.html> (last accessed March 18, 2024) (“Some Baby Food May Contain Toxic Metals”).

“diminish[es] quality of life, reduce[s] academic achievement, and disturb[s] behavior, with profound consequences for the welfare and productivity of entire societies.”¹⁸

46. The Heavy Metals “can harm a baby’s developing brain and nervous system” and cause negative impacts such as “the permanent loss of intellectual capacity and behavioral problems like attention-deficit hyperactivity disorder (‘ADHD’).”¹⁹ Even when trace amounts are found in food, these Heavy Metals can alter the developing brain and erode a child’s intelligence quotient (“IQ”).²⁰

47. Heavy Metals can remain in one’s body for years and, thus, can accumulate in the body, such as in the kidneys and other internal organs, increasing the risk to a person over time.²¹

48. Due to their smaller physical size and still-developing brain and organs, infants and toddlers are particularly susceptible to the toxic effects of Heavy Metals because “[t]hey also absorb more of the heavy metals that get into their bodies than adults do.”²²

49. Of additional concern to developing infants are the health risks related to simultaneous exposure to multiple Heavy Metals as “co-exposures can have interactive adverse effects.”²³ Heavy Metals disturb the body’s metabolism and cause “significant changes in various

¹⁸ HBBF Report, *supra*, at 13.

¹⁹ *Id.* at 6.

²⁰ Congressional Committee Report, *supra*, at 1.

²¹ Consumer Reports, *Heavy Metals in Baby Food: What You Need to Know* (Aug. 16, 2018, updated Sept. 29, 2021), available at <https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/> (last accessed April 12, 2024) (“Consumer Reports: Heavy Metals in Baby Food”).

²² *Id.*

²³ Morello-Frosch R., Cushing L.J., Jesdale B.M., Schwartz J.M., Guo W., Guo T., Wang M., Harwani S., Petropoulou S.E., Duong W., Park J.S., Petreas M., Gajek R., Alvaran J., She J., Dobraca D., Das R., Woodruff T.J. *Environmental Chemicals in an Urban Population of Pregnant Women and Their Newborns from San Francisco*. Environ Sci Technol. 2016 Nov 15;50(22):12464-12472. doi: 10.1021/acs.est.6b03492. Epub 2016 Oct 26. PMID: 27700069;

biological processes such as cell adhesion, intra- and inter-cellular signaling, protein folding, maturation, apoptosis, ionic transportation, enzyme regulation, and release of neurotransmitters.”²⁴

50. Exposure to Heavy Metals, even in small amounts, can lead to life-long effects. According to Victor Villarreal, Ph.D., Assistant Professor in the Department of Educational Psychology at the University of Texas at San Antonio who has studied the effects of heavy metals on childhood development, “[t]he effects of early exposure to heavy metals can have long-lasting impacts that may be impossible to reverse.”²⁵

51. Because Heavy Metals can bioaccumulate in the body, even regular consumption of small amounts can increase the material risk of various health issues, including the material risk of bladder, lung, and skin cancer; cognitive and reproductive problems; and type 2 diabetes.²⁶

52. As Dr. James E. Rogers, the director of food safety research and testing at Consumer Reports has said “[t]here is no safe level of heavy metals, so the goal should be to have no measurable levels of any heavy metal in baby and toddler foods.”²⁷ This rings particularly true when considering that generally, babies who are 12 months or younger heavily rely on infant

PMCID: PMC6681912. Available at <https://stacks.cdc.gov/view/cdc/80511> (last accessed March 18, 2024).

²⁴ Jaishankar, M., Tseten, T., Anbalagan, N., Mathew, B. B., & Beeregowda, K. N. (2014). *Toxicity, Mechanism and Health Effects of Some Heavy Metals*. Interdisciplinary toxicology, 7(2), 60–72. Available at <https://doi.org/10.2478/intox-2014-0009> (last accessed March 18, 2024).

²⁵ Consumer Reports: Heavy Metals in Baby Food, *supra*.

²⁶ *Id.*

²⁷ Consumer Reports, *Congressional Report Finds More Problems With Heavy Metals in Baby Food*, updated Oct. 2021, available at <https://www.consumerreports.org/food-safety/problems-with-heavy-metals-in-baby-food-congressional-report-a6400080224/#:~:text=%E2%80%9CThere%20is%20no%20safe%20level,research%20and%20testing%20at%20CR> (last accessed March 18, 2024) (emphasis added).

formula as a key source of nutrients and that unless breastmilk is an option, formula is the only food babies younger than five months can eat for their development and growth.

53. Research continues to confirm that exposures to food containing arsenic, cadmium, and lead cause “troubling risks for babies, including cancer and lifelong deficits in intelligence[.]”²⁸

54. The FDA and the WHO have declared Heavy Metals “dangerous to human health, particularly to babies and children, who are most vulnerable to their neurotoxic effects.”²⁹

Arsenic

55. The Infant Formulas contain (or have a material risk of containing) arsenic, which can cause cognitive deficits in children who are exposed early in life, and even neurological problems in adults who were exposed as infants.³⁰ “[E]ven low levels of arsenic exposure can impact a baby’s neurodevelopment.”³¹ “Studies have shown that consuming products with arsenic over time can lead to impaired brain development, growth problems, breathing problems, and a compromised immune system.”³²

56. Arsenic exposure can also cause respiratory, gastrointestinal, hematological, hepatic, renal, skin, neurological and immunological effects, and damage children’s central

²⁸ HBBF Report, *supra*, at 1.

²⁹ Congressional Committee Report, *supra*, at 2.

³⁰ HBBF Report, *supra*, at 13.

³¹ Senators’ Letter to the FDA, *supra* (citing Dartmouth Toxic Metals Superfund Research Program (2021), Arsenic and Children, available at <https://sites.dartmouth.edu/arsenicandyou/arsenic-and-children/>) (last accessed March 18, 2024)).

³² *Id.*

nervous systems and cognitive development.³³ Exposure to arsenic can also cause diabetes, atherosclerosis, and cardiovascular disease.³⁴

57. Arsenic can cause cancer in humans, as well as diabetes and atherosclerosis, and potentially cardiovascular disease when ingested chronically.³⁵ Chronic exposure to arsenic has also been associated with dermatological lesions and malignancies.³⁶

58. Moreover, “[t]here is no evidence that the harm caused by arsenic is reversible.”³⁷

59. Based on the risks associated with exposure to higher levels of arsenic, both the U.S. Environmental Protection Agency (“EPA”) and FDA have set limits concerning the allowable limit of arsenic at 10 ppb for human consumption in apple juice (regulated by the FDA) and drinking water (regulated by the EPA as a maximum contaminant level). The FDA has set the maximum allowable arsenic levels in bottled water at 10 ppb of inorganic arsenic.³⁸

³³ Congressional Committee Report, *supra*, at 10.

³⁴ States J.C., Singh A.V., Knudsen T.B., Rouchka E.C., Ngalame N.O., Arteel G.E., et al. (2012) *Prenatal Arsenic Exposure Alters Gene Expression in the Adult Liver to a Proinflammatory State Contributing to Accelerated Atherosclerosis*. PLOS ONE 7(6): e38713. Available at <https://doi.org/10.1371/journal.pone.0038713> (last accessed March 18, 2024).

³⁵ *Id.*

³⁶ Genuis SJ, Schwalfenberg G, Siy A-KJ, Rodushkin I (2012) *Toxic Element Contamination of Natural Health Products and Pharmaceutical Preparations*. PLOS ONE 7(11): e49676. Available at <https://doi.org/10.1371/journal.pone.0049676> (last accessed March 18, 2024) (“Toxic Element Contamination of Natural Health Products”).

³⁷ HBBF Report, *supra*, at 3.

³⁸ Toxic Heavy Metals in Popular Baby Foods, *supra*; *see also* 21 C.F.R. §165.110(b)(4)(iii)(A).

60. Although the FDA has not set the action level for arsenic in infant formulas specifically, “the FDA prioritizes monitoring and regulating products that are more likely to be consumed by very young children.”³⁹

61. Despite this, laboratory tests indicate that Defendant sold Products containing undisclosed arsenic levels at 7.9 ppb, an amount that is especially concerning considering the amount of infant formula consumed by developing children.

Cadmium

62. The Infant Formulas also contain (or have a material risk of containing) cadmium, which has been shown to cause anemia, liver disease, and nerve or brain damage in animals that eat or drink it.

63. Cadmium is linked to neurotoxicity, cancer, and kidney, bone, and heart damage. Scientists have reported a “tripling of risk for learning disabilities and special education among children with higher cadmium exposures, at exposure levels common among U.S. children[.]”⁴⁰

64. Cadmium, like lead, “displays a troubling ability to cause harm at low levels of exposure.”⁴¹ The U.S. Department of Health and Human Services has determined that cadmium and cadmium compounds are known human carcinogens, and the EPA has likewise determined

³⁹ NutritionInsight.com, *FDA Studies Reveal Drop in Infant Rice Cereal’s Arsenic Levels* (March 9, 2020), available at <https://www.nutritioninsight.com/news/fda-studies-reveal-drop-in-infant-rice-cereals-arsenic-levels.html> (last accessed March 18, 2024).

⁴⁰ HBBF Report, *supra*, at 14.

⁴¹ *Id.*

that cadmium is a probable human carcinogen.⁴² Compounding such concerns is the fact that cadmium has a prolonged half-life as it “sequesters in [human] tissue.”⁴³

65. The EPA has set a maximum contaminant level for cadmium in drinking water of 5 ppb (see 40 C.F.R. §141.62); the FDA has set a maximum level in bottled water to 5 ppb; and the WHO set a maximum cadmium level in drinking water to 3 ppb.⁴⁴

66. Despite this, laboratory tests indicate that Defendant sold Products containing undisclosed cadmium levels as high as 6.8 ppb.

Lead

67. The Infant Formulas contain (or have a material risk of containing) lead, which is “reasonably anticipated to be [a] human carcinogen [].”⁴⁵

68. Lead exposure can seriously harm the brain and nervous system in infants and children and is associated with a range of negative health outcomes such as behavioral problems, decreased cognitive performance, delayed puberty, and reduced postnatal growth.

69. Exposure to lead in foods builds up over time. Build-up can and has been scientifically demonstrated to lead to the development of chronic poisoning, cancer, developmental, and reproductive disorders, as well as serious injuries to the nervous system, and other organs and body systems.

⁴² CDC, Agency for Toxic Substances and Disease Registry, *Public Health Statement for Cadmium*, available at <https://www.cdc.gov/TSP/PHS/PHS.aspx?phsid=46&toxid=15> (last accessed March 18, 2024).

⁴³ Toxic Element Contamination of Natural Health Products, *supra*.

⁴⁴ Congressional Committee Report, *supra*, at 29.

⁴⁵ American Cancer Society, *Known and Probable Carcinogens*, last revised August 14, 2019, available at <https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html> (last accessed March 18, 2024).

70. Even very low exposure levels to lead can “cause lower academic achievement, attention deficits and behavior problems. No safe level of exposure has been identified.”⁴⁶ The FDA, CDC, American Academy of Pediatrics (“AAP”), and the WHO have all stated that there is no safe level of lead.⁴⁷

71. Lead is extremely toxic, and its effects cannot be reversed or remediated.⁴⁸

72. One study found that “children age 0 to 24 months lose more than 11 million IQ points from exposure to arsenic and lead in food.”⁴⁹ Additionally, studies have established a link between lead exposure and ADHD.⁵⁰

73. Although there is no federal standard for lead in baby food, health experts, including the AAP, the Environmental Defense Fund, and Consumer Reports, have agreed that lead in baby foods should not exceed 1 ppb.⁵¹

⁴⁶ HBBF Report, *supra*, at 13.

⁴⁷ FDA, *Lead in Food and Foodwares*, available at [https://www.fda.gov/food/environmental-contaminants-food/lead-food-and-foodwares#:~:text=Although%20no%20safe%20level%20for,blood%20\(%C2%B5g%20%2FdL_\)](https://www.fda.gov/food/environmental-contaminants-food/lead-food-and-foodwares#:~:text=Although%20no%20safe%20level%20for,blood%20(%C2%B5g%20%2FdL_)) (last accessed March 18, 2024); CDC, *Health Effects of Lead Exposure*, available at <https://www.cdc.gov/nceh/lead/prevention/health-effects.htm> (last accessed March 18, 2024); AAP, *Lead Exposure in Children*, available at <https://www.aap.org/en/patient-care/lead-exposure/lead-exposure-in-children/#:~:text=How%20Much%20Lead%20is%20Safe,Prevention%20recommends%20evaluation%20and%20intervention> (last accessed March 18, 2024); WHO, *Lead Poisoning*, available at [https://www.who.int/news-room/fact-sheets/detail/lead-poisoning-and-health#:~:text=The%20neurological%20and%20behavioural%20effects,learning%20problems%20\(1\)](https://www.who.int/news-room/fact-sheets/detail/lead-poisoning-and-health#:~:text=The%20neurological%20and%20behavioural%20effects,learning%20problems%20(1)) (last accessed March 18, 2024); *see also* USA Today, *FDA: Recalled Applesauce Pouches Had Elevated Lead Levels and Another Possible Contaminant* (Jan. 5, 2024), available at <https://www.usatoday.com/story/money/food/2024/01/05/applesauce-pouch-recall-contamination-spreads/72121869007/> (last accessed March 18, 2024).

⁴⁸ Consumer Reports: Heavy Metals in Baby Food, *supra*.

⁴⁹ HBBF Report, *supra*, at 7.

⁵⁰ Congressional Committee Report, *supra*, at 12.

⁵¹ Toxic Heavy Metals in Popular Baby Foods, *supra*.

74. Despite this, laboratory tests indicate Defendant sold products containing undisclosed lead levels as high as 6.5 ppb.⁵²

75. The Heavy Metals – arsenic, cadmium, and lead – are significant detriments to children.

76. The FDA has acknowledged that “exposure to [these heavy] metals are [sic] likely to have the most significant impact on public health.”⁵³

77. Importantly, however, and relevant to this lawsuit, the FDA’s action levels do not require disclosure of the presence of Heavy Metals on the packaging of products that are placed in the market. Action levels only set limits for determining when products cannot be placed into the market.

78. The presence of Heavy Metals and/or other undesirable toxins or contaminants in baby foods have been confirmed by investigations and reports by the U.S. Congress, Healthy Babies Bright Futures,⁵⁴ Consumer Reports,⁵⁵ and Politico,⁵⁶ and studies by the FDA,⁵⁷ University of Miami, the Clean Label Project, and Ellipse Analytics.⁵⁸

⁵² HBBF Report, *supra*, at 20, 34.

⁵³ FDA, *Environmental Contaminants in Food*, available at <https://www.fda.gov/food/chemical-contaminants-pesticides/environmental-contaminants-food> (last accessed March 18, 2024) (“Environmental Contaminants in Food”).

⁵⁴ HBBF Report at 12, 20, *supra*.

⁵⁵ Consumer Reports: Heavy Metals in Baby Food, *supra*.

⁵⁶ Politico, *The FDA’s Food Failure* (Apr. 8, 2022), available at <https://www.politico.com/interactives/2022/fda-fails-regulate-food-health-safety-hazards/> (last accessed March 18, 2024).

⁵⁷ FDA, *FDA Total Diet Study Report, Fiscal Years 2018-2020 Elements Data* (July 2022), available at <https://www.fda.gov/media/159751/download?attachment> (last accessed March 18, 2024) (“FDA Total Diet Study”).

⁵⁸ Gardener, et al., *Lead and Cadmium Contamination In A Large Sample of United States Infant Formulas and Baby Foods*, 651 SCI. TOTAL ENVIRON. 1, 822-827 (2019), available at:

79. Both the Congressional Committee Report, published on February 4, 2021, which acknowledged that Heavy Metals “can endanger infant neurological development,”⁵⁹ followed by a second report published on September 29, 2021, revealed alarming levels of Heavy Metals in baby foods.⁶⁰ The Congressional Committee Report acknowledged that Heavy Metals—including arsenic, cadmium, and lead—were present in “significant levels” in numerous commercial baby food products.⁶¹

80. As such, the knowledge of the risks associated with exposure to Heavy Metals is not a new phenomenon. Defendant knew or should have known the risks associated with the presence of Heavy Metals in foods consumed by infants,⁶² and that, over time, these toxins can accumulate and remain in infants’ bodies, to their detriment.

81. Despite the material risk and/or presence of these harmful chemicals, Defendant fails to disclose the presence (or risk) of Heavy Metals in its Products.

<https://www.sciencedirect.com/science/article/abs/pii/S0048969718334442?via%3Dihub> (last accessed March 18, 2024) (“Lead and Cadmium Contamination in Infant Formulas and Baby Foods”).

⁵⁹ Laura Reiley, *New Report Finds Toxic Heavy Metals in Popular Baby Foods. FDA Failed to Warn Consumers of Risk*, The Washington Post (Feb. 4, 2021), available at <https://www.washingtonpost.com/business/2021/02/04/toxic-metals-baby-food/> (last accessed March 18, 2024) (“Toxic Heavy Metals in Popular Baby Foods”).

⁶⁰ Congressional Committee Report, *supra*; Second Congressional Committee Report, *supra*.

⁶¹ Congressional Committee Report, *supra*.

⁶² See, e.g., *FDA Compliance Program Guidance Manual: Toxic Elements in Food and Foodware, and Radionuclides in Food- Import and Domestic*, available at <http://wayback.archive-it.org/7993/20170404233343/https://www.fda.gov/downloads/Food/ComplianceEnforcement/UCM073204.pdf> (last accessed March 18, 2024); see also 21 CFR §172, available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=172&showFR=1> (last accessed March 18, 2024).

II. DEFENDANT FALSELY MARKETED ITS INFANT FORMULAS AS HEALTHY AND MADE WITH NUTRITIOUS INGREDIENTS BY OMITTING ANY MENTION OF HEAVY METALS

82. Defendant packages, labels, markets, advertises, formulates, manufactures, distributes, and sells its Infant Formulas throughout the United States, including Minnesota.

83. Defendant's Infant Formulas are available at numerous retail and online outlets. The Infant Formulas are widely advertised.

84. On its website, Defendant markets its Infant Formulas as the “#1 Trusted Brand of Pediatricians & Parents,” “#1 trusted brand for brain-building nutrition and immune support,” and “#1 infant formula brand recommended by pediatricians.”⁶³



85. On its website, Defendant promises to “[s]upport your baby’s development right from the start with brain-building nutrition and MFGM components from the #1 trusted infant formula brand.”⁶⁴ Defendant represents that “using Enfamil gives you the confidence you’ve made the right choice for your baby.”⁶⁵ Defendant boasts and reassures parents of the quality of its products, claiming “we know you’ve got lots of questions. Relax. We’ve got you covered. With a

⁶³ <https://www.enfamil.com/> (last accessed March 18, 2024).

⁶⁴ <https://www.enfamil.com/enfamil-neuropro/> (last accessed March 18, 2024).

⁶⁵ <https://www.enfamil.com/why-enfamil/> (last accessed March 18, 2024).

complete family of brain-building formulas to fuel the wonder of your little one. From everyday nutrition to specialty formulas.”⁶⁶

86. Defendant touts its innovations to its Infant Formula and provides extensive information about the ingredients in its formulas to consumers throughout its website, including on its Frequently Asked Questions (“FAQ”) page.⁶⁷

87. Defendant made the decision to omit any mention of the presence or material risk of Heavy Metals in its Infant Formulas, and to instead package its Infant Formulas as healthy and made with nutritious ingredients even though Defendant had a duty to ensure that the Products’ packaging was true and not misleading.

88. Defendant also had exclusive and/or superior knowledge of the presence or material risk of Heavy Metals in its Infant Formula but chose to not inform consumers.

89. Defendant intentionally omitted from its packaging any mention of the presence (or material risk) of Heavy Metals in the Infant Formulas in order to induce and mislead reasonable consumers to purchase its Infant Formulas.

90. With Defendant marketing its Infant Formulas as healthy and made with nutritious ingredients to nourish babies, Defendant clearly recognizes the importance of its Infant Formula to the development of infants. Indeed, the presence or risk of undisclosed Heavy Metals defeats the purpose of infant formula, which is to nourish babies, a fact touted by Defendant.

91. As a result of the undisclosed material information on the Infant Formulas’ packaging, a reasonable consumer would have no reason to suspect the presence (or material risk)

⁶⁶ <https://www.enfamil.com/why-enfamil/enfamil-formula-family/> (last accessed March 18, 2024).

⁶⁷ <https://www.enfamil.com/help-center/nutrients-ingredients/> (last accessed March 18, 2024).

of Heavy Metals in the Infant Formulas without conducting his or her own scientific tests (which are time consuming and expensive) or reviewing third-party scientific testing of these Products.

III. DUE TO THE PRESENCE AND MATERIAL RISK OF HEAVY METALS IN THE INFANT FORMULAS, THE PACKAGING WAS MATERIALLY MISLEADING

92. At all times during the Relevant Period, Defendant knew or should have known the Infant Formulas contained undisclosed Heavy Metals and were not sufficiently tested for the presence and material risk of Heavy Metals.

93. Defendant's Infant Formulas contained undisclosed levels of Heavy Metals due to Defendant's failure to monitor for the presence of Heavy Metals in its Products and their ingredients. Defendant was aware of this risk and failed to disclose it to Plaintiffs and the Class despite having a duty to disclose.

94. Despite the known risks of exposure to Heavy Metals, Defendant has intentionally, recklessly, and/or knowingly sold the Infant Formulas without disclosing to consumers, like Plaintiffs and the Class, the presence or material risk of Heavy Metals.

95. Defendant knew or should have known that Heavy Metals pose health risks to infants.

96. Defendant knew or should have known that it owed consumers a duty of care to prevent or, at the very least, minimize the presence of Heavy Metals in the Infant Formulas to an undetectable level.

97. Defendant knew or should have known it owed consumers a duty of care to adequately test for Heavy Metals in the Infant Formulas and their ingredients.

98. Defendant knew consumers purchased the Infant Formulas based on the reasonable expectation that Defendant manufactured the Infant Formulas to the highest standards. In fact, Defendant promised as much – at length – on its website:

Our products meet or exceed all **infant formula requirements set out by the FDA**, which are among the **most rigorous** in the food industry. Each of our manufacturing facilities adheres to safety guidelines among the **most rigorous in the food industry** and our own **stringent quality standards** so that we can assure the highest quality products. Parents can be assured that our infant formulas are safe and nutritious feeding options for their infants when prepared, stored, and handled according to package directions.

Our infant products undergo **extensive quality and safety checks** throughout the manufacturing process—from raw materials to finished product. A representative number of samples from every batch we produce are tested to ensure the product meets our **stringent quality standards**. Each batch of our products is assured to meet our **high quality and safety standards** as verified by our **proprietary Quality Systems** that exist in every manufacturing facility. We distribute our products only if they pass our **strict testing**. We track the path of every ingredient in our infant and toddler products from its initial supplier through all processing stages until it reaches our consumer.

The [FDA] has very **specific and rigorous manufacturing standards** for infant formulas and toddler drinks that we adhere to. All Mead Johnson formulas are in compliance with all FDA regulations, including Enfamil® NeuroPro™, Enfamil® Enspire™, Enfamil® Gentlelease®, and Nutramigen®. Our products meet or exceed all **infant formula requirements set out by the FDA**, which are among the **most rigorous** in the food industry. The amounts of ingredients in Enfamil Infant Formulas are all within required guidelines established to ensure the safety and nutritional quality of infant formulas. **We are committed to the most stringent manufacturing, packaging, and quality assurance procedures.**⁶⁸

(Emphasis supplied.) Based on consumers' expectation that Defendant manufactured the Infant Formulas to the highest standards, Defendant knew or should have known consumers reasonably inferred that Defendant would hold the Infant Formulas to the highest standards for preventing the inclusion of Heavy Metals in the Infant Formulas, which would include testing the Products and their ingredients for Heavy Metals.

⁶⁸ <https://www.enfamil.com/why-enfamil/quality-assurance/> (last accessed March 18, 2024).

99. A recent consumer survey done by Plaintiffs' counsel ("Consumer Survey") demonstrates such an expectation.⁶⁹

Consumer Survey	Yes	No
Do you expect a company to test for arsenic, cadmium, lead, and/or mercury in infant formula that will be fed to infants?	91.1%	8.9%
Would you expect a company to disclose if there were detectable levels, or risk, of arsenic, cadmium, lead, and/or mercury in an infant formula?	91.3%	8.7%

100. Further, Defendant has recognized consumer concern for the possible presence of Heavy Metals in baby food products and infant formulas. As a member of the Infant Nutrition Council of America ("INCA") through its parent company Reckitt Benckiser Group PLC, Defendant joined two other major manufacturers of infant formula products to lobby against the promulgation of California Assembly Bill 899 ("AB 899") in 2023.⁷⁰ As introduced, the original version of AB 899 would have required infant formula manufacturers – like Defendant – to test for Heavy Metals in their products and disclose the testing results on the packaging.⁷¹ INCA vehemently opposed any disclosure of Heavy Metals to consumers, arguing the proposed measure

⁶⁹ All Consumer Survey respondents were parents 18 and over with children aged anywhere from 0 to 4 years old from a majority of states, including Illinois, California, and Minnesota, and all of whom had purchased infant formula within the past 3 years.

⁷⁰ Analysis of AB 899 as amended March 13, 2023, available at <https://billtexts.s3.amazonaws.com/ca/ca-analysishttps-leginfo-legislature-ca-gov-faces-billAnalysisClient-xhtml-bill-id-202320240AB899-ca-analysis-357755.pdf> (last accessed March 18, 2024) ("Analysis of AB 899").

⁷¹ *Id.*

would “create confusion”⁷² among consumers and “create fear and panic,”⁷³ and cause them to “mistrust” the manufacturers.⁷⁴ Furthermore, INCA has argued that such requirements would cause consumers to change their purchasing behaviors.⁷⁵

101. Based on the foregoing, reasonable consumers, like Plaintiffs, would consider the inclusion (or material risk of inclusion) of Heavy Metals a material fact when considering what infant formulas to purchase.

102. Defendant knew that monitoring for Heavy Metals in its Infant Formulas and their ingredients was not only important, but also critical.

103. Defendant also knew that monitoring Heavy Metals was likewise important to its consumers to protect their babies.

IV. INFANT FORMULAS CAN BE MANUFACTURED WITHOUT MEASURABLE LEVELS OF HEAVY METALS

104. In contrast to the levels of Heavy Metals found in Defendant’s Infant Formulas, other infant formula manufacturers have produced formula products that have non-detectable levels of Heavy Metals.

105. The Clean Label Project tests products for more than 400 contaminants, including heavy metals, chemicals, and plastics, and presents its Purity Award to companies with products with the lowest levels of the contaminants when compared to other products in a given category.⁷⁶

⁷² *Id.*; see also Analysis of AB 899 as amended April 12, 2023, available at <https://trackbill.com/s3/bills/CA/2023/AB/899/analyses/senate-health.pdf> (last accessed April 12, 2024) (“Analysis of AB 899 as amended April 12, 2023”).

⁷³ Analysis of AB 899.

⁷⁴ *Id.*

⁷⁵ See Analysis of AB 899 as amended April 12, 2023, available at <https://trackbill.com/s3/bills/CA/2023/AB/899/analyses/senate-health.pdf> (last accessed March 18, 2024).

⁷⁶ Clean Label Project Purity Award, available at <https://cleanlabelproject.org/purity-award/> (last accessed March 18, 2024).

106. Bobbie, a manufacturer of infant formula (recognized by the Clean Label Project for manufacturing products that were free from detectable levels of Heavy Metals) was a recipient of the Clean Label Project's Purity Award.⁷⁷

107. Plaintiffs' counsel had Bobbie Organic Infant Formula independently tested and that testing confirmed the presence of Heavy Metals at non-detectable levels:

Infant Formula	Arsenic (ppb)	Cadmium (ppb)	Lead (ppb)
Bobbie Organic Infant Formula	< 2.2	< 1.3	< 1.0

108. This testing confirms infant formula manufacturers can manufacture infant formulas with Heavy Metals levels that are not measurable.

109. Additionally, testing by Consumer Reports identified baby food products with Heavy Metal levels low enough to not cause concern, as well as some products with Heavy Metal levels that were not measurable.⁷⁸ “[T]here are ways for [baby food] manufacturers to significantly reduce or eliminate these [heavy] metals from their products.”⁷⁹

110. In testing conducted by Consumer Reports, other products had non-detectable levels of Heavy Metals.⁸⁰ As stated by Dr. James E. Rogers, the Consumer Reports Director of Food Safety Research and Testing, “Every category of food was represented in that lower-risk

⁷⁷ Business Wire, *Bobbie is First-Ever Infant Formula to Receive the Clean Label Project Purity Award and Certification as a Pesticide-Free Product* (Jan. 25, 2022), available at <https://www.businesswire.com/news/home/20220125005905/en/Bobbie-Is-First-Ever-Infant-Formula-To-Receive-The-Clean-Label-Project-Purity-Award-and-Certification-as-a-Pesticide-Free-Product> (last accessed March 18, 2024).

⁷⁸ Consumer Reports: Heavy Metals in Baby Food, *supra*.

⁷⁹ *Id.*

⁸⁰ *Id.*

group. That indicates that there are ways for manufacturers to significantly reduce or eliminate these [heavy] metals from their products.”⁸¹

111. In the FDA Total Diet Study, it was also demonstrated that infant formulas can be manufactured without detectable levels of Heavy Metals.⁸²

112. Moreover, because of public health efforts, exposure to lead has consistently and notably decreased over the past 40 years.⁸³ These efforts include increasing awareness of the dangers of even low levels of lead exposure to young children.⁸⁴ The progress towards decreasing childhood exposure to lead was so impressive that the CDC identified “childhood lead poisoning prevention as 1 of 10 great U.S. public health achievements during 2001 to 2010.”⁸⁵

113. Defendant knew or should have known it could control the levels of Heavy Metals in the Infant Formulas in order to achieve non-detectable or zero levels by adequately monitoring its ingredients for Heavy Metals and adjusting any formulation to reduce ingredients that contained Heavy Metals.

114. Defendant also knew it was not adequately monitoring and testing for Heavy Metals in the Infant Formulas and their ingredients. Defendant knew its failure to adequately monitor and test for Heavy Metals in the Infant Formulas and their ingredients continued throughout the Relevant Period.

⁸¹ *Id.*

⁸² FDA Total Diet Study, *supra*, at 73, 81-82.

⁸³ Dignam, T., Kaufmann, R. B., LeStourgeon, L., & Brown, M. J. (2019). *Control of Lead Sources in the United States, 1970-2017: Public Health Progress and Current Challenges to Eliminating Lead Exposure*. Journal of Public Health Management and Practice: JPHMP, 25 Suppl 1, Lead Poisoning Prevention (Suppl 1 LEAD POISONING PREVENTION), S13–S22. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6522252/#R6> (last accessed March 18, 2024).

⁸⁴ *Id.*

⁸⁵ *Id.*

115. Defendant's marketing was misleading due to its failure to properly and sufficiently monitor and test for Heavy Metals and/or for its failure to disclose on the packaging of the Products the presence (or material risk) of Heavy Metals in the Infant Formulas.

116. Defendant knew or should have known consumers paid a price premium for its Products and expected Defendant to test and monitor for Heavy Metals and disclose on the packaging of the Products the presence or material risk of Heavy Metals in the Infant Formulas and their ingredients.

117. At all times during the Relevant Period, Defendant did not monitor or test for Heavy Metals in the Infant Formulas and their ingredients and Defendant did not disclose on the packaging of the Products the presence or material risk of Heavy Metals.

118. Defendant knew or should have known that consumers reasonably expected it to test for and monitor the presence of Heavy Metals in the Infant Formulas and their ingredients, and to disclose the presence or material risk of any levels of Heavy Metals in its Products.

119. Defendant knew or should have known the Infant Formulas contained or risked containing Heavy Metals that were inconsistent with its marketing.

120. Defendant knew or should have known that, in order to comply with its marketing, consumers expected it to ensure the Infant Formulas and their ingredients were monitored and tested for Heavy Metals, and to disclose the presence (or material risk) of Heavy Metals.

121. Defendant knew, yet failed to disclose, its lack of adequate testing and/or knowledge of the risk or presence of Heavy Metals in the Infant Formulas' and their ingredients.

122. Defendant's Omissions are false, misleading, and crafted to deceive the public as they create an image that the Infant Formulas are nutritious and safe from the risk or presence of

Heavy Metals. The presence or risk of Heavy Metals defeats the purpose of the Infant Formulas, which is nutrition for infants.

123. Moreover, reasonable consumers, such as Plaintiffs and the Class members, would have no reason to doubt Defendant's statements regarding the quality of the Products. Defendant's nondisclosure and/or concealment of the presence (or risk) of Heavy Metals in the Infant Formulas alleged herein intended to and did, in fact, cause consumers like Plaintiffs and the Class members, to purchase Products they would not have if the true quality of the Products and their ingredients were disclosed.

V. DEFENDANT'S PACKAGING MISLED REASONABLE CONSUMERS BASED ON THE MATERIAL OMISSIONS

124. Defendant's packaging communications misled and deceived reasonable consumers because Defendant actively and knowingly concealed and failed to disclose that the Infant Formulas contained (or had a material risk of containing) Heavy Metals, while representing nutritious quality and characteristics.

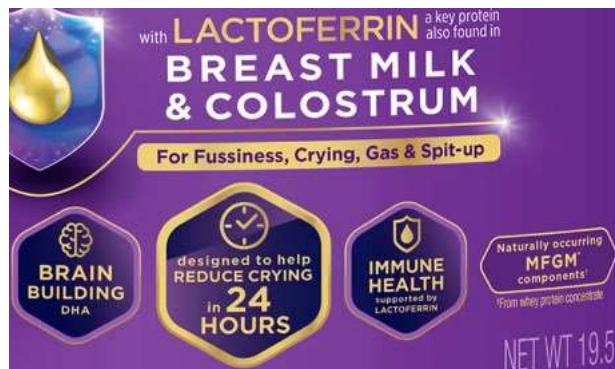
125. Based on the impression given by the packaging communications and Omissions, no reasonable consumer could expect or understand that the Infant Formulas contained (or had a material risk of containing) Heavy Metals.

126. The Infant Formula packaging communications include, but are not limited to:

(a) Enfamil® A.R.: “BRAIN BUILDING,” “expert-recommended,” “#1 ADDED RICE starch formula,” “#1 RECOMMENDED BRAND BY PEDIATRICIANS,” “Calcium for strong bones,” and “Vitamin C for immune support.”



(b) Enfamil® Enspire Gentlelease: “with LACTOFERRIN a key protein also found in BREAST MILK & COLOSTRUM,” “BRAIN BUILDING,” “IMMUNE HEALTH supported by LACTOFERRIN,” and “Naturally occurring MFGM components.”



(c) Enfamil® Gentlelease: “BRAIN BUILDING,” “expert-recommended,” and “#1 RECOMMENDED BRAND BY PEDIATRICIANS.”



(d) Enfamil® NeuroPro: “EXCLUSIVE HuMO6 IMMUNE BLEND,” “BRAIN BUILDING,” “expert-recommended,” “inspired by BREAST MILK,” “supports IMMUNE HEALTH,” “naturally-occurring MFGM components,” “#1 RECOMMENDED BRAND BY PEDIATRICIANS,” and “Beta Carotene & DHA for baby’s eye health”.



(e) Enfamil® NeuroPro Sensitive: “BRAIN BUILDING,” “expert-recommended,” “HMO for IMMUNE SUPPORT,” “NON-GMO No Artificial Growth Hormones,” and “#1 RECOMMENDED BRAND BY PEDIATRICIANS.”



(f) Enfamil® Nutramigen: “BRAIN BUILDING,” “#1 RECOMMENDED BRAND BY PEDIATRICIANS” (front and back), “THE ONLY HYPOALLERGIC FORMULA WITH LGG® PROBIOTIC” (front and back), “NO ARTIFICIAL GROWTH HORMONES,” and “LGG® probiotic to help support digestive health.”



(g) Enfamil® ProSobee: “No artificial colors, flavors or sweeteners” (front), “BRAIN BUILDING,” “expert-recommended,” “IMMUNE HEALTH Vitamins A, C, E & Selenium” (front), “#1 RECOMMENDED BRAND BY PEDIATRICIANS,” “NO ARTIFICAL colors, flavors or sweeteners” (back), and “vitamins A, C & E for IMMUNE SUPPORT” (back).



127. Based on Defendant's Omissions from these communications on the Products' packaging, no reasonable consumer could expect or understand that the Infant Formulas contained (or had a material risk of containing) Heavy Metals.

128. The Omissions wrongfully convey to consumers that Defendant's Infant Formulas have certain nutritious quality and characteristics that they do not actually possess.

129. For instance, although Defendant misleadingly causes consumers to believe its Infant Formulas do not contain Heavy Metals due to the material Omissions, the Infant Formulas do in fact contain undisclosed Heavy Metals, which is material information to reasonable consumers.

130. Plaintiffs' counsel had seven of Defendant's Infant Formulas tested and that testing confirmed the presence of undisclosed Heavy Metals at the following levels:

Infant Formula	Arsenic (ppb)	Cadmium (ppb)	Lead (ppb)
Enfamil® A.R.	3.4	3.2	1.2
Enfamil® Gentlelease	3.7	2.6	1.7
Enfamil® Enspire Gentlease	5.0	2.3	< 1.0
Enfamil® NeuroPro	< 2.2	2.0	< 1.0
Enfamil® NeuroPro Sensitive	5.1	< 1.3	2.3
Enfamil® Nutramigen	7.9	4.6	6.5
Enfamil® ProSobee	6.7	6.8	3.5

131. Independent testing also confirmed Heavy Metals in two of Defendant's Products:⁸⁶

Infant Formula	Arsenic (ppb)	Cadmium (ppb)	Lead (ppb)
Enfamil ProSobee Soy Infant Formula	6.2*	6.9	7.8
Enfamil Infant – Infant Formula Milk-Based with Iron, 0-12 months	< 2.2	0.7*	2.0

⁸⁶ HBBF Report, *supra*, at 20.

132. Regardless of the levels found, the testing shows detectable presence of Heavy Metals when, as stated herein, no level of Heavy Metals is safe.⁸⁷

133. Based on the Omissions, a reasonable consumer would not expect the presence of Heavy Metals, nor would a reasonable consumer be able to detect the presence of Heavy Metals in the Infant Formulas without conducting his or her own scientific tests or reviewing scientific testing conducted on the Products.

134. In fact, the FDA recently requested \$1.2 billion from the U.S. Congress for its Foods Program for initiatives such as reduction of heavy metals in foods for infants and young children.⁸⁸ A portion of the funding would be for educational outreach about heavy metals in foods.⁸⁹

135. Reasonable consumers must and do rely on Defendant to honestly report what its Infant Formulas contain.

136. Plaintiffs relied on the Products' packaging when making her purchasing decisions.

137. Plaintiffs' expectations and reliance are consistent with reasonable consumers as shown by the Consumer Survey recently done by Plaintiffs' counsel:

Consumer Survey	No	Yes
After seeing the label would you expect arsenic, cadmium, lead, and/or mercury in the infant formula?	77.8%	22.2%

⁸⁷ Some Baby Food May Contain Toxic Metals, *supra*.

⁸⁸ Department of Health and Human Services Fiscal Year 2023: *Food and Drug Administration, Justification of Estimates for Appropriations Committees*, available at <https://www.fda.gov/media/157192/download?attachment> (last accessed March 18, 2024).

⁸⁹ *Id.*

Consumer Survey	Very important	Important	Not at all important
Please select how important, if at all, would it be to your purchasing decision if the infant formula you purchased contained, or risked containing, even a small amount of arsenic, cadmium, lead, and/or mercury.	71.0%	25.4%	3.6%

138. In light of Defendant's communications regarding the quality of the Infant Formulas and its commitment to innovative formulas and nutritious ingredients, Defendant knew or should have known the Infant Formulas or their ingredients contained or risked containing Heavy Metals.

139. Defendant had a duty to ensure the Infant Formulas were not deceptively, misleadingly, unfairly, and/or falsely marketed and all material information was properly and fully disclosed. For example, as the FDA recently stated in connection with the recall of applesauce due to the presence of lead, "Companies have the responsibility to take steps to assure that the products they manufacture are not contaminated with unsafe levels of heavy metals."⁹⁰ Notably, the FDA acknowledges that there is "no known safe level of exposure to lead."⁹¹

⁹⁰ Christina Jewett and Will Fitzgibbon, *Lead-Tainted Applesauce Sailed Through Gaps in Food-Safety System*, N.Y. Times, Feb. 27, 2024, available at <https://www.nytimes.com/2024/02/27/world/europe/lead-applesauce-food-safety.html?smid=nytcore-ios-share&referringSource=articleShare> (last accessed Mar. 18, 2024).

⁹¹ Lead in Food and Foodwares, FDA, March 6, 2024, available at [https://www.fda.gov/food/environmental-contaminants-food/lead-food-and-foodwares#:~:text=Although%20no%20safe%20level%20for,blood%20\(%C2%B5g%20%2FdL%20%\)](https://www.fda.gov/food/environmental-contaminants-food/lead-food-and-foodwares#:~:text=Although%20no%20safe%20level%20for,blood%20(%C2%B5g%20%2FdL%20%)) (last accessed March 18, 2024).

140. Defendant acted knowingly, recklessly, and/or intentionally with its deceptive packaging based on the material Omissions.

141. Defendant knew that properly and sufficiently monitoring for Heavy Metals in the Products and their ingredients was not only important, but also critical.

142. Additionally, Defendant knew or should have been aware that a reasonable consumer would be feeding the Infant Formula multiple times each day to his or her baby, making it a significant source of food and nutrition for the child. This leads to an infant's repeated exposure to the Heavy Metals, which defeats the purpose of infant formula, *i.e.*, to provide nourishment to infants.

143. Finally, Defendant knew or should have known it could control the levels of Heavy Metals in the Infant Formulas by properly monitoring their ingredients for Heavy Metals and adjusting any formulation to reduce ingredients that contained or risked containing Heavy Metals.

144. The Omissions are material and reasonably likely to deceive reasonable consumers, such as Plaintiffs, in their purchasing decisions. This is true especially considering the long-standing campaign by Defendant to market the Infant Formulas as healthy and made with nutritious ingredients, and to induce consumers, such as Plaintiffs, to purchase the Products.

145. The Omissions make the Infant Formulas' packaging deceptive. Reasonable consumers, like Plaintiffs, would consider the facts that Infant Formula contained (or had a material risk of containing) Heavy Metals when considering what infant formula to purchase.

146. At all times during and throughout the Relevant Period, Defendant knew it was not following proper manufacturing standards and not sufficiently and consistently monitoring or testing the Infant Formulas or their ingredients for Heavy Metals.

147. Defendant's packaging was misleading due to Defendant's failure to disclose the true quality of the Infant Formulas based on its improper manufacturing processes and the presence or material risk of the presence of Heavy Metals.

148. Defendant knew or should have known the Infant Formulas contained or risked containing undisclosed levels of Heavy Metals that were inconsistent with Defendant's packaging.

149. Defendant knew or should have known that reasonable consumers expected it to have strong and adequate manufacturing processes and ensure the Infant Formulas and their ingredients were monitored and tested for Heavy Metals to ensure compliance with Defendant's packaging.

150. Defendant knew or should have known consumers paid premium prices because the Omissions were not disclosed.

151. The Omissions are material and render the Infant Formulas' packaging deceptive as without full disclosure, reasonable consumers believe the Infant Formulas are high quality, healthy, and nutritious products.

152. Moreover, reasonable consumers, such as Plaintiffs and the Class members, would have no reason to doubt or question Defendant's statements regarding the quality of the Infant Formulas. Based on the impression given by the packaging, no reasonable consumer could expect or understand the Infant Formula contained (or had a material risk of containing) Heavy Metals.

153. The Omissions were intended to and did, in fact, cause consumers like Plaintiffs and the members of the Class to purchase products they would not have if the true quality of the Products and their ingredients were disclosed or for which they would not have paid a premium price.

154. As a result of Defendant's deceptive packaging of the Infant Formulas, Defendant was able to generate substantial sales, which allowed Defendant to capitalize on, and reap enormous profits from, consumers who paid the purchase price or premium for the Infant Formulas that were not as advertised.

**PLAINTIFFS' RELIANCE WAS REASONABLE
AND FORESEEN BY DEFENDANT**

155. Plaintiffs read and relied upon the packaging of the Infant Formulas when making their purchasing decisions. Had they known Defendant omitted and failed to disclose the Infant Formula contained (or had a material risk of containing) Heavy Metals, they would not have purchased the Infant Formulas.

156. A reasonable consumer would consider the packaging of a product when deciding whether to purchase it.

**DEFENDANT'S KNOWLEDGE AND
NOTICE OF ITS BREACH OF ITS IMPLIED WARRANTIES**

157. Defendant had sufficient notice of its breach of implied warranties. Defendant has, and had, exclusive knowledge of manufacturing processes, quality control policies, the physical and chemical make-up of the Infant Formulas, and whether the Products and their ingredients contained Heavy Metals.

158. In 2017 and 2019, the Clean Label Project published results and findings from an investigation of heavy metals in baby and toddler food products, including infant formula. The findings showed the presence of Heavy Metals in Defendant's Infant Formulas. In response to the

Clean Label Project's study, Defendant stated that it "specifically monitors the presence of many materials, including arsenic, cadmium, [and] lead . . . to ensure 'safety and high quality.'"⁹²

159. Moreover, Defendant was put on notice by February and September of 2021, when Congress publicly released findings regarding the presence of Heavy Metals in baby foods.⁹³ The FDA has also released a study showing the presence of Heavy Metals in baby foods, including infant formulas.⁹⁴

160. Defendant was likewise given notice through its membership in INCA, for example, through INCA's lobbying efforts in opposition to AB 899 that would have required infant formula manufacturers to test for and disclose levels of Heavy Metals.⁹⁵

161. Similarly, Defendant was made aware that it failed to implement or maintain proper manufacturing and quality control measures for detecting and controlling the presence of adulterating substances through the FDA's investigations from 2017 to 2023 and the multiple recalls by Defendant in 2023 alone due to bacterial contamination of its formula products.

162. Defendant has not changed its packaging to include any disclaimer on the Omissions.

⁹² USA Today, *These Baby Foods and Formulas Tested Positive for Arsenic, Lead, and BPA in New Study* (Oct. 25, 2017), available at <https://www.usatoday.com/story/news/nation-now/2017/10/25/these-baby-foods-and-formulas-tested-positive-arsenic-lead-and-bpa-new-study/794291001/> (last accessed March 18, 2024).

⁹³ Congressional Committee Report, *supra*; Second Congressional Committee Report, *supra*.

⁹⁴ FDA Total Diet Study, *supra*, at 73, 81-82.

⁹⁵ Analysis of AB 899, *supra*.

PRIORITY EXISTS WITH PLAINTIFFS AND THE PROPOSED CLASS

163. Defendant knew that reasonable consumers such as Plaintiffs and the proposed Class members would be the end purchasers of the Infant Formulas and the targets of its advertising, marketing, packaging, and statements.

164. Defendant intended that the packaging and implied warranties would be considered by the end purchasers of the Infant Formulas, including Plaintiffs and the proposed Class members.

165. Defendant directly marketed to Plaintiffs and the proposed Class through its packaging.

166. Plaintiffs and the proposed Class members are the intended beneficiaries of the implied warranties.

**APPLICABILITY OF EQUITABLE TOLLING AND
THE DISCOVERY RULE TO THE STATUTE OF LIMITATIONS**

167. Fraudulent concealment and/or the discovery rule toll Plaintiffs' claims.

168. The statute of limitations is tolled for all of Plaintiffs' statutory consumer protection and common law claims due to Defendant's fraudulent concealment of facts that the Infant Formulas contained (or had a material risk of containing) Heavy Metals. Defendant intentionally concealed these material facts from Plaintiffs.

169. Defendant knew the Omissions were a material consideration for any parent buying infant formulas.

170. Defendant violated the relevant state consumer fraud acts by deceiving customers as to the true nature, quality, and makeup of the Infant Formulas.

171. Based on Defendant concealing material facts from Plaintiffs, Plaintiffs could not reasonably discover that the Infant Formula contained (or had a material risk of containing) Heavy Metals.

172. Plaintiffs did not know that the Infant Formula contained (or had a material risk of containing) Heavy Metals. Instead, Defendant only represented that the Infant Formulas were healthy, nutritious, and made of high-quality ingredients to support growing infants.

CLASS ACTION ALLEGATIONS

173. Plaintiffs bring this action individually and on behalf of the following Class:

All persons who are residents of Minnesota who, from May 1, 2018, to the present, purchased the Infant Formulas in Minnesota for household use, and not for resale (the “Class”).

174. Excluded from the Class are the Defendant, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, all governmental entities, and any judge, justice, or judicial officer presiding over this matter.

175. This action is brought and may be properly maintained as a class action. There is a well-defined community of interests in this litigation and the members of the Class are easily ascertainable.

176. Defendant engaged in a common course of conduct giving rise to the legal rights sought to be enforced by Plaintiffs individually and on behalf of the other members of the Class. Identical statutory violations and business practices and harm are involved. Individual questions, if any, are not prevalent in comparison to the numerous common questions that dominate this action.

177. The requirements for class certification have been met pursuant to Rule 23.01 of the Minnesota Rules of Civil Procedure as follows:

(a) the Class is so numerous that joinder of all members is impracticable and the disposition of the claims of the members of all Class in a single action will provide substantial benefits to the parties and Court;

(b) Questions of law and fact common to the Class predominate over any questions affecting only individual members of the Class, including:

- 1) whether Defendant owed a duty of care;
- 2) whether Defendant owed a duty to disclose;
- 3) whether Defendant knew or should have known that the Infant Formulas and their ingredients contained or risked containing Heavy Metals;
- 4) whether Defendant failed to disclose the Omissions;
- 5) whether the claims of the Plaintiffs and the Class serve a public benefit;
- 6) whether Defendant's packaging is false, deceptive, and misleading based on the Omissions;
- 7) whether the Omissions are material to a reasonable consumer;
- 8) whether the Omissions are likely to deceive a reasonable consumer;
- 9) whether Defendant had knowledge that the Omissions were material and false, deceptive, and/or misleading;
- 10) whether Defendant breached its duty of care;
- 11) whether Defendant breached its duty to disclose;
- 12) whether Defendant violated the laws of the State of Minnesota;
- 13) whether Defendant breached its implied warranties;
- 14) whether Defendant engaged in unfair trade practices;
- 15) whether Defendant engaged in false advertising;
- 16) whether Defendant made fraudulent omissions;

- 17) whether Plaintiffs and Class members' claims are tolled based on Defendant's fraudulent concealment;
- 18) whether Plaintiffs and members of the Class are entitled to actual and statutory damages; and
- 19) whether Plaintiffs and members of the Class are entitled to declaratory and injunctive relief.

(c) Plaintiffs' claims are typical of those of the members of the Class in that they are based on the same underlying facts, events, and circumstances relating to Defendant's conduct.

(d) Plaintiffs will fairly and adequately represent and protect the interests of the Class, has no interests incompatible with the interests of the Class, and has retained counsel competent and experienced in class action, consumer protection, and false advertising litigation.

(e) Class treatment is superior to other options for resolution of the controversy because the relief sought for each member of the Class is small such that, absent representative litigation, it would be infeasible for members of the Class to redress the wrongs done to them.

178. As a result of the foregoing, class treatment is appropriate.

CLAIMS FOR RELIEF

COUNT I

Violations of Minnesota Unlawful Trade Practices Act, Minn. Stat. §325D.13, *et seq.*, Against Defendant on Behalf of Plaintiffs and the Class

179. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

180. Defendant is a "person" within the meaning of the Minnesota Unlawful Trade Practices Act ("MUTPA").

181. Defendant violated the MUTPA by knowingly failing to disclose the Omissions.

182. Defendant knew or should have known the Infant Formulas and their ingredients were not of the true quality advertised because they contained (or had a material risk of containing) Heavy Metals.

183. Defendant's pattern of knowing concealment, Omissions, and other deceptive conduct were likely to deceive or cause misunderstanding and did in fact deceive Plaintiffs and the Class with respect to the Infant Formulas' quality, nature of the ingredients, and suitability for consumption by infants with no development or health risks.

184. Defendant intended for Plaintiffs and the Class to rely on its Omissions, concealment, implied warranties, and/or deceptions regarding the Infant Formulas' quality, nature of the ingredients, and suitability for consumption.

185. Defendant's conduct and Omissions described herein occurred repeatedly in its trade or business and were capable of deceiving a substantial portion of the consuming public.

186. Defendant was under a duty to disclose the Omissions because Defendant undertook the disclosure of information about the Infant Formulas on the Infant Formulas' packaging.

187. Defendant failed to discharge its duty to disclose the Omissions.

188. The facts concealed, omitted, or not disclosed by Defendant were material facts in that Plaintiffs, the Class, and any reasonable consumer would have considered them in deciding whether to purchase the Infant Formulas. Had Plaintiffs and the Class known the Infant Formulas did not have the quality advertised by Defendant, they would not have purchased the Infant Formulas or paid the premium price.

189. Defendant's unlawful conduct is continuing, with no indication that it intends to cease this fraudulent course of conduct.

190. As a direct and proximate result of Defendant's conduct, Plaintiffs and the Class suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

191. Plaintiffs and the members of the Class would not have purchased the Infant Formulas at all had they known that Infant Formulas do not conform to the packaging.

192. Pursuant to Minn. Stat. §8.31, subd. 3a, and §325D.15, Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available thereunder for Defendant's violations of the MUTPA.

COUNT II

Violations of Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. §325D.44, *et seq.*, Against Defendant on Behalf of Plaintiffs and the Class

193. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

194. Defendant is a "person" within the meaning of the Minnesota Uniform Deceptive Trade Practices Act ("MUDTPA").

195. Defendant willingly engaged in deceptive trade practices, in violation of the MUDTPA, by failing to disclose the Omissions.

196. Defendant knew or should have known the Infant Formulas contained (or had a material risk of containing) Heavy Metals.

197. Defendant's Omissions, concealment, and other deceptive conduct were likely to deceive or cause misunderstanding and did in fact deceive Plaintiffs and the Class with respect to the Infant Formulas' ingredients, uses, benefits, standards, quality, grade, and suitability for consumption by infants with no development or health risks.

198. Defendant intended that Plaintiffs and the Class would rely on Defendant's Omissions, concealment, implied warranties, and/or deceptions regarding the Infant Formulas' ingredients, uses, benefits, standards, quality, grade, and suitability for consumption by infants with no development or health risks.

199. Defendant's conduct and Omissions described herein occurred repeatedly in its trade or business and were capable of deceiving a substantial portion of the consuming public.

200. The facts concealed or not disclosed by Defendant were material facts in that Plaintiffs, the Class, and any reasonable consumer would have considered them in deciding whether to purchase the Infant Formulas. Had Plaintiffs and the Class known the Infant Formulas did not have the quality advertised by Defendant, they would not have purchased the Infant Formulas.

201. Defendant intended that Plaintiffs and the Class would rely on Defendant's Omissions, concealment, and other deceptive conduct when purchasing the Infant Formulas, unaware of the undisclosed material facts. This conduct constitutes consumer fraud.

202. Defendant's unlawful conduct is continuing, with no indication it intends to cease this fraudulent course of conduct.

203. Defendant was under a duty to disclose the Omissions because Defendant undertook the disclosure of information about the Infant Formulas on the Infant Formulas' packaging.

204. Defendant failed to discharge its duty to disclose the Omissions about the Infant Formulas.

205. As a direct and proximate result of Defendant's conduct, Plaintiffs and the Class suffered actual damages by: (1) paying a premium price for Products they reasonably believed did

not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

206. Plaintiffs and the members of the Class would not have purchased the Infant Formulas at all had they known of the Omissions.

207. Pursuant to Minn. Stat. §8.31, subd. 3a, and §325D.45, Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available thereunder for Defendants' violations of the MUDTPA.

COUNT III

Violations of Minnesota False Statement in Advertising Act, Minn. Stat. §325F.67, *et seq.*, Against Defendant on Behalf of Plaintiffs and the Class

208. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

209. Plaintiffs and the Class purchased "goods," specifically the Infant Formulas discussed herein, and are a "person" within the meaning of the False Statement in Advertising Act ("FSAA").

210. Plaintiffs and the Class purchased the Infant Formulas because of the Omissions asserted on the packaging that were made, published, disseminated, circulated, and placed before the public by Defendant.

211. By engaging in the conduct as described herein, Defendant continues to violate Minn. Stat. §325F.67.

212. Defendant's Omissions and use of other deceptive business practices include, by way of example, representations that the Infant Formulas were healthy, made from nutritious ingredients, and safe for consumption by infants with no development or health risks.

213. Defendant knew or should have known the Infant Formulas did not have the quality described above because they included undisclosed (or material risk of) Heavy Metals.

214. The Omissions were likely to deceive or cause misunderstanding and did in fact deceive Plaintiffs and the Class with respect to the Infant Formulas' ingredients, uses, benefits, standards, quality, grade, and suitability for consumption by infants with no development or health risks.

215. Defendant's conduct and Omissions described herein occurred repeatedly in Defendant's trade or business and were capable of deceiving a substantial portion of the consuming public.

216. The Omissions were made to customers in Minnesota, including Plaintiffs and the Class, thus the cause of action serves the public benefit of informing Minnesota consumers that the Products contained (or had a material risk of containing) Heavy Metals.

217. The facts concealed, omitted, or not disclosed by Defendant were material facts in that Plaintiffs, the Class, and any reasonable consumer would have considered them in deciding whether to purchase the Infant Formulas. Had Plaintiffs and the Class known the Infant Formulas did not have the quality as advertised by Defendant, they would not have purchased the Infant Formulas or paid the premium price.

218. Defendant intended that Plaintiffs and the Class would rely on the deception by purchasing the Infant Formulas, unaware of the Omissions and other undisclosed material facts. This conduct constitutes consumer fraud.

219. Defendant's unlawful conduct is continuing, with no indication that it intends to cease this fraudulent course of conduct.

220. As a direct and proximate result of Defendant's conduct, Plaintiffs and the Class suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

221. Plaintiffs and the members of the Class would not have purchased the Infant Formulas at all had they known of the presence or material risk of these Heavy Metals.

222. Pursuant to Minn. Stat. §8.31, subd. 3a, and §325F.67, Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available thereunder for Defendant's violations of the FSAA.

COUNT IV

Violations of Minnesota Prevention of Consumer Fraud Act, Minn. Stat. §325F.69, et. seq., Against Defendant on Behalf of Plaintiffs and the Class

223. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

224. Plaintiffs at all times relevant hereto were citizens of the State of Minnesota.

225. Defendant is a "person" within the meaning of the Minnesota Prevention of Consumer Fraud Act ("MPCFA").

226. The Omissions were made in connection with the sale of the Infant Formulas to Plaintiffs and the Class.

227. Defendant knowingly acted, used, and employed fraud, false pretenses, and deceptive practices in connection with the sale of the Infant Formulas. Specifically, Defendant failed to disclose the Infant Formulas contained levels or material risk of Heavy Metals.

228. Defendant knew or should have known the Infant Formulas did not have the quality reasonable consumers expected because they included undisclosed (or the material risk of) Heavy

Metals that do not conform to the packaging. Defendant intended for Plaintiffs and the Class to rely on the Infant Formulas' packaging in deciding whether to purchase the Infant Formulas.

229. Defendant's unfair or deceptive acts or practices were likely to deceive reasonable consumers about the Infant Formulas' quality, nature of the ingredients, consumption by infants with no development or health risks, and, by extension, the true value of the Infant Formulas. Plaintiffs and the Class relied on, and were in fact deceived by, Defendant's Omissions with respect to the Infant Formulas' quality, nature of the ingredients, and fitness for consumption in deciding to purchase them over competitors' infant formulas.

230. The facts concealed, omitted, or not disclosed by Defendant were material facts in that Plaintiffs, the Class, and any reasonable consumer would have considered them in deciding whether to purchase the Infant Formulas. Had Plaintiffs and the Class known the Infant Formulas did not have the quality advertised by Defendant, they would not have purchased the Infant Formulas or paid the premium price.

231. Defendant's Omissions were made to customers in Minnesota, including Plaintiffs and the Class, thus the cause of action serves the public benefit of informing Minnesota consumers that the Products contained (or had a material risk of containing) Heavy Metals.

232. Defendant's unlawful conduct is continuing, with no indication that it intends to cease this fraudulent course of conduct.

233. As a direct and proximate result of Defendant's conduct, Plaintiffs and the Class suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

234. Plaintiffs and the members of the Class would not have purchased the Infant Formulas at all had they known of the presence of these Heavy Metals.

235. Pursuant to Minn. Stat. §8.31, subd. 3a, and §325F.69, Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available thereunder for Defendant's violations of the MPCFA.

COUNT V

**Breach of Implied Warranty of Merchantability, Minn. Stat. § 336.2-314,
Against Defendant on Behalf of Plaintiffs and the Class**

236. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

237. Defendant is a merchant engaging in the sale of goods to Plaintiffs and the Class.

238. There was a sale of goods from Defendant to Plaintiffs and the members of the Class.

239. At all times mentioned herein, Defendant manufactured and sold the Infant Formulas and, prior to the time the Infant Formulas were purchased by Plaintiffs and the Class, impliedly warranted that the Infant Formulas were of merchantable quality and fit for their ordinary use (consumption by infants with no development or health risks).

240. Plaintiffs and the Class relied on these implied warranties when they purchased the Infant Formulas.

241. The Infant Formulas were not fit for their ordinary use (consumption by infants with no development or health risks) as they contained (or had a material risk of containing) Heavy Metals that do not conform to the packaging.

242. These promises became part of the basis of the bargain between Defendant and Plaintiffs and members of the Class, and thus constituted implied warranties.

243. Defendant breached the implied warranties by selling Infant Formulas that contain (or risk containing) Heavy Metals.

244. Defendant was on notice of this breach as it was aware of the inclusion (or risk) of Heavy Metals.

245. Privity exists because Defendant impliedly warranted to Plaintiffs and the members of the Class through the Products' packaging, that the Infant Formulas were healthy, nutritious, and safe for consumption.; however, Defendant failed to mention or disclose the Infant Formulas contained (or had a material risk of containing) Heavy Metals.

246. As a direct and proximate result of Defendant's breach of its implied warranties, Plaintiffs and the Class suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

247. On January 26, 2024, Dominique Lopez sent Defendant a letter on behalf of herself and all other United States citizens, who purchased the Infant Formulas notifying Defendant of its breaches of warranty and demanding that Defendant rectify the problems stated herein before filing her complaint in the district court in Northern District of Illinois, which Plaintiff Seutter joined.⁹⁶ Defendant received sufficient notice in advance before filing of this case through the pre-suit letter and through the pleading but has failed to rectify or agree to rectify the problems associated with the actions detailed above.

⁹⁶ See Complaint, Lopez et al. v. Mead Johnson Nutrition Co. et al., No. 1:24-cv-00691 (N.D. Ill. Jan. 26, 2024)

248. Plaintiffs, on behalf of themselves and the Class, seeks actual damages for Defendant's failure to deliver goods that conform to their implied warranties and resulting breach.

COUNT VI

Fraud by Omission against Defendant on Behalf of Plaintiffs and the Class

249. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

250. Defendant knew or should have known the Infant Formulas were contained (or had a material risk of containing) Heavy Metals.

251. Plaintiffs and the Class and Defendant acted within the context of a business transaction when Plaintiffs and the Class purchased Defendant's Infant Formulas for household or business use, and not for resale.

252. Plaintiffs and the Class were ordinary non-business consumers.

253. Defendant actively and knowingly concealed from and failed to disclose to Plaintiffs and the Class that the Infant Formulas contained (or had a material risk of containing) Heavy Metals that do not conform to the Products' packaging.

254. As an infant formula manufacturer, Defendant is in a special position of trust upon which consumers rely.

255. Defendant was under a duty to disclose to Plaintiffs and the Class the true quality, characteristics, nature of the ingredients, and suitability of the Infant Formulas because:

(a) Defendant was in a superior position to know the true state of facts about its Products;

(b) Defendant was in a superior position to know the nature of the ingredients, characteristics and suitability of the Infant Formulas for consumption by infants with no development or health risks; and

(c) Defendant knew that Plaintiffs and the Class could not reasonably have been expected to learn about the Omissions without Defendant disclosing it on the Infant Formulas' packaging.

256. Defendant knows its customers trust the quality of its products and expect Defendant's Infant Formulas to be free of the risk or presence of Heavy Metals. Defendant also knows that consumers seek out and wish to purchase infant formulas that possess high quality ingredients free of toxins, contaminants, or chemicals, and that these consumers will pay for infant formulas that they believe possess these qualities.

257. Due to the Omissions on the Infant Formulas' packaging, Defendant had a duty to disclose the whole truth that the Infant Formulas contained (or had a material risk of containing) Heavy Metals.

258. Defendant acted in bad faith when it intended that Plaintiffs and the Class would rely on the Omissions when purchasing the Infant Formulas, unaware of the undisclosed material facts.

259. Defendant was under a duty to disclose the Omissions because Defendant undertook the disclosure of information about the Infant Formulas on the Infant Formulas' packaging.

260. Defendant failed to discharge its duty to disclose the Omissions.

261. Defendant allowed the Omissions on the Products' packaging to intentionally mislead consumers, such as Plaintiffs and the Class.

262. The facts concealed, omitted, or not disclosed by Defendant to Plaintiffs and the Class are material in that a reasonable consumer would have considered the Omissions material when deciding whether to purchase the Infant Formulas.

263. Defendant knew or should have known the Omissions were material to Plaintiffs and the Class's decisions to purchase the Infant Formulas and would induce Plaintiffs and the Class to purchase the Infant Formulas.

264. Defendant intentionally concealed its improper manufacturing conditions and the presence or material risk of Heavy Metals in the Infant Formulas with the intent to defraud and deceive Plaintiffs and the Class.

265. Plaintiffs and the Class justifiably relied on Defendant's Omissions to their detriment. The detriment is evident from the true quality, characteristics, and nature of the ingredients of the Infant Formulas, which is misleading when compared to the Infant Formulas' packaging and represented by Defendant and inherently unfair to consumers of the Infant Formulas, such as Plaintiffs and the Class.

266. As a direct and proximate result of Defendant's conduct, Plaintiffs and the Class suffered actual damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

267. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

COUNT VII
Fraudulent Misrepresentation by Omission against Defendant
on Behalf of Plaintiffs and the Class

268. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

269. Plaintiffs and members of the Class were buyers and Defendant was a seller in a commercial exchange.

270. Plaintiffs and the Class were ordinary non-business consumers who trusted Defendant to manufacture, distribute, market, and sell Infant Formulas that did not contain (or have a material risk of containing) Heavy Metals.

271. As an infant formula manufacturer, Defendant is in a special position of trust upon which consumers rely.

272. Defendant knowingly and actively concealed the Omissions from Plaintiffs and the Class.

273. Defendant intentionally, knowingly, and/or recklessly made these Omissions to induce Plaintiffs and the Class to purchase the Infant Formulas.

274. Defendant knew or should have known the Infant Formulas contained (or had a material risk of containing) Heavy Metals.

275. Defendant allowed its packaging to intentionally mislead consumers, such as Plaintiffs and the Class.

276. Defendant's packaging did not disclose the Omissions with the intent to deceive and defraud consumers, such as Plaintiffs and the Class.

277. Defendant intended for Plaintiffs and the Class to rely on the Omissions. Defendant knows its customers trust the quality of its Products and that it is in a special position of trust with the public.

278. Defendant knows reasonable consumers expected the Infant Formulas to not contain (or have a material risk of containing) Heavy Metals.

279. Defendant also knows that reasonable consumers seek out and wish to purchase infant formulas that possess high quality ingredients free of toxins, contaminants, or chemicals, and that these consumers will pay for infant formulas they believe possess these qualities.

280. Defendant knew that Plaintiffs and the Class were ignorant of the Omissions.

281. Defendant knew that Plaintiffs and the Class could not reasonably have been expected to learn or discover the Omissions.

282. Defendant was under a duty to disclose the Omissions regarding its Infant Formulas to Plaintiffs and the Class because:

(a) Defendant was in possession of special facts that could not have been discovered by Plaintiffs and the Class.

(b) Defendant's packaging was misleading to consumers by failing to disclose the Omissions.

(c) Based on Defendant's partial statements on the Infant Formulas' packaging that gave a misleading impression to reasonable consumers without further information about the Omissions, Defendant assumed the obligation to make a full and fair disclosure of the whole truth.

283. The Omissions were material facts to Plaintiffs and the Class, as Plaintiffs and the Class relied on the Omissions when purchasing the Infant Formulas.

284. Plaintiffs and the Class had a right to rely on Defendant's packaging as the truth because customers like Plaintiffs and the Class trust the quality of Defendant's Products and they expect the Infant Formulas do not contain (or have a material risk of containing) Heavy Metals.

285. Plaintiffs and the Class did in fact rely on the material Omissions and purchased the Infant Formulas to their detriment. Given the materiality of the Omissions, Plaintiffs and the Class's reliance on the Omissions was justifiable.

286. As a direct and proximate result of Defendant's conduct, Plaintiffs and the Class suffered actual pecuniary damages by: (1) paying a premium price for Products they reasonably believed did not contain (or have a material risk of containing) Heavy Metals; (2) purchasing Products they would not have purchased had Defendant's Omissions been disclosed; and/or (3) receiving Products that were worthless because they contained or risked containing Heavy Metals.

287. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

COUNT VIII

Unjust Enrichment Against Defendant on Behalf of Plaintiffs and the Class

288. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

289. Substantial benefits have been conferred on Defendant by Plaintiffs and the Class through the purchase of the Infant Formulas. Defendant knowingly and willingly accepted and enjoyed these benefits.

290. Defendant either knew or should have known that the payments rendered by Plaintiffs and the Class were given and received with the expectation that the Infant Formulas would not contain (or have a material risk of containing) Heavy Metals. As such, it would be inequitable for Defendant to retain the benefit of the payments under these circumstances.

291. Defendant was obligated to disclose the Omissions in the Infant Formulas because (1) it had exclusive knowledge they contained (or had a material risk of containing) Heavy Metals; (2) the Omissions were not known or reasonably accessible to Plaintiffs and the Class; (3) Defendant actively concealed the Omissions; and (4) Defendant made partial statements on the

Infant Formulas' packaging that gave a misleading impression to Plaintiffs and the Class and reasonable consumers without further information because the Omissions were not disclosed.

292. Defendant's acceptance and retention of the benefits of the payments from Plaintiffs and the Class under the circumstances alleged herein make it inequitable for Defendant to retain the benefits without payment of the value to Plaintiffs and the Class.

293. Plaintiffs and the Class are entitled to recover from Defendant all amounts wrongfully collected and improperly retained by Defendant, plus interest thereon.

294. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, pray for judgment against the Defendant as to each and every count, including:

1. An order declaring this action to be a proper class action pursuant to Minnesota Rule of Civil Procedure 23, appointing Plaintiffs and their counsel to represent the Class, and requiring Defendant to bear the costs of class notice;
2. An order enjoining Defendant from selling the Infant Formulas until the Heavy Metals are at a non-detectable level;
3. An order enjoining Defendant from selling the Infant Formulas until the Omissions are disclosed;
4. An order enjoining Defendant from selling the Infant Formulas in any manner suggesting or implying that they are healthy and made from nutritious ingredients;
5. An order requiring Defendant to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief;

6. An order awarding declaratory relief, and any further injunctive relief permitted by law or equity, including enjoining Defendant from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendant's conduct;
7. An order requiring Defendant to pay restitution to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, untrue or misleading advertising, or a violation of the state laws, plus pre- and post-judgment interest thereon;
8. An order requiring Defendant to disgorge or return all monies, revenues, and profits obtained by means of any wrongful or unlawful act or practice;
9. An order requiring Defendant to pay all actual and statutory damages permitted under the counts alleged herein;
10. An order awarding attorneys' fees and costs to Plaintiffs and the Class; and
11. An order providing for all other such equitable relief as may be just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: May 3, 2024

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By: /s/ Catherine K. Smith

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**ACKNOWLEDGEMENT REQUIRED BY MINNESOTA STATUTE, SECTION 549.211,
SUBDIVISION 2**

The undersigned hereby acknowledges that pursuant to Minnesota Statute, section 549.211, subdivision 2, costs, disbursements and reasonable attorney and witness fees may be awarded to the opposing party or parties in this litigation if the Court should find that the undersigned acted in bad faith, asserted a claim or defense that is frivolous and that is costly to the other party, asserted an unfounded position solely to delay the ordinary course of the proceedings or to harass or committed a fraud upon the Court.

Dated: May 3, 2024

/s/ Catherine K. Smith

Catherine K. Smith